



Patent  
Attorney's Docket No. 032994-099

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
Joel Douglas et al.	)	Group Art Unit: 3763
Application No.: 10/642,346	)	Examiner: Unassigned
Filed: August 18, 2003	)	Confirmation No.: 2054
For: MICRO INFUSION DRUG DELIVERY	)	
DEVICE	)	
	)	
	)	
	)	

**INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$ \_\_\_\_\_ as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$ \_\_\_\_\_ as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \$ \_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \$ \_\_\_\_\_ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, LLP

Date: May 3, 2004

By: \_\_\_\_\_

David R. Heckadon  
Registration No. 50,184

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(650) 622-2300



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of )  
Joel Douglas et al. ) Group Art Unit: 3763  
Application No.: 10/642,346 ) Examiner: Catherine Serke  
Filed: August 18, 2003 ) Confirmation No.: Unassigned  
For: INFUSION DRUG DELIVERY DEVICE )  
)  
)  
)  
)

**FIRST**  
**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Some of the listed documents were previously made of record in prior Application Serial No. 09/845,256, filed May 1, 2001, upon which for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98, a copy of each of the listed documents, except those documents which were previously made of record in the prior application, is enclosed.

**U.S. Patent Documents**

3,595,231	Pistor	07/1971
3,814,097	Ganderton et al.	06/1974
3,963,380	Thomas, Jr. et al.	06/1976
3,964,482	Gerstel et al.	06/1976
3,964,484	Reynolds et al.	06/1976
4,235,234	Whitney et al.	11/1980
4,276,878	Storz	07/1981
4,313,439	Babb et al.	02/1982
4,493,704	Beard et al.	01/1985



U.S. Patent Documents (Cont.)

4,645,495	Vaillancourt	02/1987
4,741,736	Brown	05/1988
4,813,939	Marcus	09/1989
4,856,340	Garrison	08/1989
4,865,591	Sams	09/1989
4,883,472	Michel	11/1989
4,969,871	Theeuwes et al.	11/1990
4,973,318	Holm et al.	11/1990
5,017,190	Simon et al.	05/1991
5,026,357	Przuntek et al.	06/1991
5,261,882	Sealfon	11/1993
5,279,586	Balkwill	01/1994
5,327,033	Guckel et al.	07/1994
5,330,431	Heskowitz	07/1994
5,354,279	Hofling	10/1994
5,391,250	Cheney II et al.	02/1995
5,419,777	Holfing	05/1995
5,437,999	Diebold et al.	08/1995
5,464,395	Faxon et al.	11/1995
5,587,326	Takemura	12/1996
5,637,095	Nason et al.	06/1997
5,640,995	Packard et al.	06/1997
5,644,177	Guckel et al.	07/1997
5,697,901	Eriksson	12/1997
5,716,343	Kriesel et al.	02/1998
5,914,507	Polla et al.	06/1999
5,957,889	Poulsen et al.	09/1999
5,964,729	Choi et al.	10/1999
5,997,501	Gross et al.	12/1999
6,016,693	Viani et al.	01/2000

U.S. Patent Documents (Cont.)

6,022,316	Eppstein et al.	02/2000
6,050,988	Zuck	04/2000
6,083,196	Trautman et al.	07/2000
6,132,755	Eicher et al.	10/2000
6,256,533	Yuzhakov et al.	07/2001
6,302,870	Jacobsen et al.	10/2001
6,482,186	Douglas et al.	11/2002
6,629,949	Douglas et al.	10/2003

Foreign Patent Documents

0 295 075	EP	12/1988
0 323 321	EP	07/1989
0 916 353	EP	05/1999
0 937 475	EP	08/1999
2 628 636	FR	09/1989
WO 93/17754	PCT	09/1993
WO 95/09021	PCT	04/1995
WO 96/38190	PCT	12/1996
WO 97/36623	PCT	10/1997
WO 98/57688	PCT	12/1998
WO 99/47341	PCT	09/1999
WO 99/64580	PCT	12/1999
WO 99/16833	PCT	03/2000
WO 00/35530	PCT	06/2000

Non Patent Literature Documents

Tamborlane, W., et al., "Reduction to Normal of Plasma Glucose in Juvenile Diabetes by Subcutaneous Administration of Insulin with a Portable Infusion Pump," The New England Journal of Medicine, 1979, vol. 300, pp. 573-578

Albisser, A.M., et al., "A Portable Precision Pumping System for Chronic, Programmed Insulin Infusion", Medical Progress Through Technology, 1978, Vol. 5, pp. 187-193

Irsigler, et al., "Long-Term Continuous Intravenous Insulin Therapy with a Portable Insulin Dosage-regulating Apparatus", Diabetes, 1979, Vol. 28, pp. 196-203

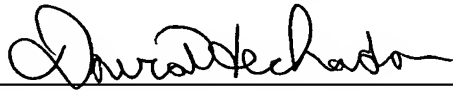
The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b) no fee or statement is required.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, LLP

Date: May 3, 2004

By:   
David R. Heckadon  
Registration No. 50,184

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(650) 622-2300

Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT NO.  
032994-099APPLICATION NO.  
10/642,346FIRST INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Joel Douglas et al.FILING DATE  
August 18, 2003GROUP  
3763

MAY 03 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	3,595,231		Pistor	07/1971
	3,814,097		Ganderton et al.	06/1974
	3,963,380		Thomas, Jr. et al.	06/1976
	3,964,482		Gerstel et al.	06/1976
	3,964,484		Reynolds et al.	06/1976
	4,235,234		Whitney et al.	11/1980
	4,276,878		Storz	07/1981
	4,313,439		Babb et al.	02/1982
	4,493,704		Beard et al.	01/1985
	4,645,495		Vaillancourt	02/1987
	4,741,736		Brown	05/1988
	4,813,939		Marcus	09/1989
	4,856,340		Garrison	08/1989
	4,865,591		Sams	09/1989
	4,883,472		Michel	11/1989
	4,969,871		Theeuwes et al.	11/1990
	4,973,318		Holm et al.	11/1990
	5,017,190		Simon et al.	05/1991
	5,026,357		Przuntek et al.	06/1991
	5,261,882		Sealfon	11/1993
	5,279,586		Balkwill	01/1994
	5,327,033		Guckel et al.	07/1994
	5,330,431		Herskowitz	07/1994
	5,354,279		Hofling	10/1994
	5,391,250		Cheney II et al.	02/1995
	5,419,777		Hofling	05/1995
	5,437,999		Diebold et al.	08/1995
	5,464,395		Faxon et al.	11/1995
	5,587,326		Takemura	12/1996
	5,637,095		Nason et al.	06/1997
	5,640,995		Packard et al.	06/1997
	5,644,177		Guckel et al.	07/1997
	5,697,901		Eriksson	12/1997
	5,716,343		Kriesel et al.	02/1998
	5,914,507		Polla et al.	06/1999
	5,957,889		Poulsen et al.	09/1999
	5,964,729		Choi et al.	10/1999
	5,997,501		Gross et al.	12/1999
	6,016,693		Viani et al.	01/2000
	6,022,316		Eppstein et al.	02/2000
	6,050,988		Zuck	04/1900
	6,083,196		Trautman et al.	07/1900

Substitute for forms 1449A/PTO & 1449B/PTO	ATTORNEY'S DKT NO. 032994-099	APPLICATION NO. 10/642,346
	APPLICANT Joel Douglas et al.	
	FILING DATE August 18, 2003	GROUP 3763
	<b>FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	

U.S. PATENT DOCUMENTS				
	6,132,755		Eicher et al.	10/2000
	6,256,533		Yuzhakov et al.	07/2001
	6,302,870		Jacobsen et al.	10/2001
	6,482,186		Douglas et al.	11/2002
	6,629,949		Douglas et al.	10/2003

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes	No
	0 295 075		EP	12/1988		
	0 323 321		EP	07/1989		
	0 916 353		EP	05/1999		
	0 937 475		EP	08/1999		
	2 628 636		FR	09/1989		
	WO 93/17754		PCT	09/1993		
	WO 95/09021		PCT	04/1995		
	WO 96/38190		PCT	12/1996		
	WO 97/36623		PCT	10/1997		
	WO 98/57688		PCT	12/1998		
	WO 99/47341		PCT	09/1999		
	WO 99/64580		PCT	12/1999		
	WO 00/16833		PCT	03/2000		
	WO 00/35530		PCT	06/2000		

NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Tamborlane, W., et al., "Reduction to Normal of Plasma Glucose in Juvenile Diabetes by Subcutaneous Administration of Insulin with a Portable Infusion Pump," The New England Journal of Medicine, 1979, vol. 300, pp. 573-578
	Albisser, A.M., et al., "A Portable Precision Pumping System for Chronic, Programmed Insulin Infusion", Medical Progress Through Technology, 1978, Vol. 5, pp. 187-193
	Irsigler, et al., "Long-Term Continuous Intravenous Insulin Therapy with a Portable Insulin Dosage-regulating Apparatus", Diabetes, 1979, Vol. 28, pp. 196-203

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT NO.  
032994-099APPLICATION NO.  
10/642,346FIRST INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Joel Douglas et al.FILING DATE  
August 18, 2003GROUP  
3763

MAY 03 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	3,595,231		Pistor	07/1971
	3,814,097		Ganderton et al.	06/1974
	3,963,380		Thomas, Jr. et al.	06/1976
	3,964,482		Gerstel et al.	06/1976
	3,964,484		Reynolds et al.	06/1976
	4,235,234		Whitney et al.	11/1980
	4,276,878		Storz	07/1981
	4,313,439		Babb et al.	02/1982
	4,493,704		Beard et al.	01/1985
	4,645,495		Vaillancourt	02/1987
	4,741,736		Brown	05/1988
	4,813,939		Marcus	09/1989
	4,856,340		Garrison	08/1989
	4,865,591		Sams	09/1989
	4,883,472		Michel	11/1989
	4,969,871		Theeuwes et al.	11/1990
	4,973,318		Holm et al.	11/1990
	5,017,190		Simon et al.	05/1991
	5,026,357		Przuntek et al.	06/1991
	5,261,882		Sealfon	11/1993
	5,279,586		Balkwill	01/1994
	5,327,033		Guckel et al.	07/1994
	5,330,431		Herskowitz	07/1994
	5,354,279		Hofling	10/1994
	5,391,250		Cheney II et al.	02/1995
	5,437,999		Diebold et al.	08/1995
	5,464,395		Faxon et al.	11/1995
	5,569,272		Reed et al.	10/1996
	5,587,326		Takemura	12/1996
	5,637,095		Nason et al.	06/1997
	5,640,995		Packard et al.	06/1997
	5,644,177		Guckel et al.	07/1997
	5,697,901		Eriksson	12/1997
	5,716,343		Kriesel et al.	02/1998
	5,914,507		Polla et al.	06/1999
	5,957,889		Poulsen et al.	09/1999
	5,964,729		Choi et al.	10/1999
	5,997,501		Gross et al.	12/1999
	6,016,693		Viani et al.	01/2000
	6,022,316		Eppstein et al.	02/2000
	6,050,988		Zuck	04/1900
	6,083,196		Trautman et al.	07/1900



Substitute for forms 1449A/PTO &amp; 1449B/PTO

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

ATTORNEY'S DKT NO.  
032994-099

APPLICATION NO.  
10/642,346

APPLICANT  
Joel Douglas et al.

FILING DATE  
August 18, 2003

GROUP  
3763

## **U.S. PATENT DOCUMENTS**

	6,132,755		Eicher et al.	10/2000
	6,256,533		Yuzhakov et al.	07/2001
	6,302,870		Jacobsen et al.	10/2001
	6,482,186		Douglas et al.	11/2002
	6,629,949		Douglas et al.	10/2003

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes	No
	0 937 475		Europe	08/1999		
	2 628 636		France	09/1989		
	WO 93/17754		PCT	09/1993		
	WO 95/09021		PCT	04/1995		
	WO 96/38190		PCT	12/1996		
	WO 97/36623		PCT	10/1997		
	WO 98/57688		PCT	12/1998		
	WO 99/47341		PCT	09/1999		
	WO 99/64580		PCT	12/1999		
	WO 00/16833		PCT	03/2000		
	WO 00/35530		PCT	06/2000		

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Tamborlane, W., et al., "Reduction to Normal of Plasma Glucose in Juvenile Diabetes by Subcutaneous Administration of Insulin with a Portable Infusion Pump," The New England Journal of Medicine, 1979, vol. 300, pp. 573-578

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.